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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/322,732 05/28/99 MAROTTI K PUJ-0041

026657 HM12/0119
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EXAMINER

ROBINSON, H

ART UNIT

PAPER NUMBER

1653

11

DATE MAILED:

01/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/322,732

Applicant(s)
Marotti et al.

Examiner
Hope Robinson

Group Art Unit
1653



☒ Responsive to communication(s) filed on Nov 2, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-141 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-8, 15-18, 140, and 141 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6, 10

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

1. Applicant's election without traverse of Group I (claims 1-8, 15-18 and 140-141) in Paper No. 9 is acknowledged.

Information Disclosure Statement

2. The information disclosure statement filed on December 10, 1999 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP 609 because there are items listed on the information disclosure statement are missing from the application. In addition, there are serial numbers of applications listed on the information disclosure that were not considered since they are not considered to be printed publications or materials. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. A line has been drawn through the following items on the information disclosure statement: references by Bashford et al., Lakowicz et al. and the National Committee for Clinical Laboratory Standards (applicant had a footnote indicating that these references were not provided because they were easily obtainable by the Examiner). In addition, all of the applications listed on pages 7-10 were also not considered.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-8, 15-18 and 140-141 are rejected under 35 U.S.C. 112 first paragraph, because the specification is not enabled for the full scope of the claims. The claimed invention is directed to new methods or procedures to screen for, detect and/or characterize new compounds that modulate the function of efp in prokaryotic cells. These methods or procedures include new in vitro methods as well as new in vivo methods (see page 4). However, the specification provides only examples and no specific assays to accompany the claimed method. Furthermore there is no indicia of how the claimed method is an improvement over the prior art. See for example on page 14 where the specification states that cell-free extract is an example of an assay that can be performed. In addition, the specification asserts that contacting can take place in buffers or media well known to those skilled in the art. Further, varying amounts of the test compound can be used as desired by the practitioner. Therefore, it appears that the new method encompasses a lot of old methods and that much of the parameters involved in the method can be adjusted arbitrarily.

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Additionally, the specification asserts that the claimed method will identify a compound that modulates the activity of prokaryotic efp, determine whether the compound modifies activity of efp, for example determining if the compound binds to efp by a number of art-recognized procedures (i.e. binding assays such as gel-shift mobility electrophoresis, Western blot, filter binding and scintillation proximity assay). Note that the claimed method is relying on art-recognized procedures, yet the specification asserts that this is a new method/procedure. Furthermore, the information provided in the specification is exemplary and not limiting, therefore, does not breathe life into the claims. In view of the foregoing, one skilled in the art would have to engage in undue experimentation to be able to practice the full scope of the claims since the specification does not provide sufficient detail.

In the absence of sufficient guidance/direction regarding the steps to determine whether the test compound modulates the activity of efp one skilled in the art would not be able to practice the claimed invention commensurate in scope with the claims. In addition, the claims broadly recite a method of identifying a compound that modulates the activity of efp, however, there is no specific assay and measurements to obtain this information nor information as to whether modulation is up or down (see for example claim 1). Note for example that the prior art teaches that genes encoding certain ribosomal proteins can be deleted from the chromosome without an apparent effect on cell viability. It is also stated that most initiation, elongation and termination factors are required for cellular growth, however, some of these proteins may be dispensable under certain growth conditions (Aoki et al., The Journal of Biological Chemistry,

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vol. 272, no. 51, 1997). In view of the prior art the specification needs to provide guidance as to how the compound is determined, what the compound is, how the efp activity will be modulated, what effect the modulation will have on the function of the efp and a specific assay and measurement steps to achieve all of the above.

Absent exemplification of a specific assay to assay a specific compound the specification is not enabled for a method that modulates the activity of efp. Further, since no guidance or direction is provided regarding the determination of the test compound it would require undue experimentation to be able to practice the claimed invention.

Thus, for all of the above reasons, the specification is not considered to be enabling without undue experimentation, because, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to enable one skilled in the art to be able to practice the invention commensurate in scope with these claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-8, 15-18 and 140-141 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1 is indefinite because the claim recites a method that modulates the activity of prokaryotic elongation factor p. However, the claim does not recite whether modulation will be upward or downward. The claim is further indefinite because the claim recites “determining whether said compound modifies activity of efp” and there is no indication of how, no measurement steps are included in the method (see also the dependent claims). Note also that the compound to be identified is not named or described.

Claim 6 is indefinite because the claim recites the phrase “compound interfering with the function of efp is interfering with other protein” and it is unclear whether “interfering” is negative or positive or what extent the compound is interfering. Furthermore, the “other protein” is not described or named.

Claim 7 is indefinite because the claim recites “L16 protein” and the acronym is not preceded by the spelled out meaning of “L16” (see also claims 140 and 141).

Claim 15 is indefinite because the claim depends from two non-elected claims. The dependent claims are also included in this rejection.

Conclusion

5. No claims are allowable.

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hope A. Robinson whose telephone number is (703)308-6231. The Examiner can normally be reached on Monday - Friday from 9:00 A.M. to 5:30 P.M. (EST).

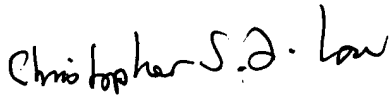
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Christopher S.F. Low, can be reached at (703)308-2932.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-2742. Please affix the Examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope A. Robinson, MS 

Patent Examiner


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